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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,607	06/24/2003	Gregory S. Hamilton	054707-1225	8963

29728 7590 04/28/2004

GUILFORD PHARMACEUTICALS C/O
FOLEY & LARDNER
3000 K STREET, NW
WASHINGTON, DC 20007-5143

EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Celia Chang

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 71-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 71-85 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

☐ International Summary (PTO 413)

☐ PTO Form 100 (PTO 100)

DETAILED ACTION

1. A preliminary amendment was filed. Claims 1-71 have been canceled. Claims 72-85 have been added and pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 72-74, 75, in part, 76-77, 80 being drawn to compounds wherein R2 is hetereocyclic/quinone ring, classified in class 548, subclass various, depending on species election.
- II. Claims 78-79, drawn to multiple active ingredients composition, one is a compound of claim 76, classified in class 514, subclass various, depending on species election. If this group is elected a further election of a single disclosed composition, one is a compound of claim 76, is also required.
- III. Claims 75 in part, drawn to compounds wherein R2 is nonhetereocyclic, classified in class 548, subclass various, depending on species election. If this group is elected, a further election of a single disclosed compound is also required.
- IV. Claims 81-82, drawn to composition comprising a compound of claim 80 formula I, classified in class 514, subclass various depending on species election. If this group is elected, a further election of a single disclosed species of composition is also required.
- V. Claims 83-85, drawn to multiple active ingredients composition wherein one is a compound of claim 80 formula I, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a

single composition wherein one is a compound of claim 80 formula I is also required.

The inventions are distinct, each from the other because of the following reasons:

The inventions are distinct, each from the other because:

The compounds of groups I and III are independent and distinct because compounds of group I contain at least two heterocyclic rings while compounds of group II have R2 being carboxylic acid, sulfonic acid etc. The compounds of the two groups differ in elements, bonding arrangement and chemical properties that unpatentability of one group would not necessary imply unpatentability of another. Groups II, IV-V are compositions containing patentably distinct compounds or multiple active ingredients. The merit for patentability of patentably independent and distinct compounds or multiple active ingredients i.e. patentability of the combination of active ingredients, are not identical to the merit determination of compounds per se i.e. elements, bonding arrangement and chemical properties. The searches for each group is not co-extensive of another and separate examination must be conducted.

Should applicant traverse on the ground that the groups/species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups/species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the


application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Apr. 22, 2004


Celia Chang
Primary Examiner
Art Unit 1625